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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,236	09/25/2000	Jurgen Wolfrum	8070-PA01	4280

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EXAMINER

SIEW, JEFFREY

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 11/26/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/669,936

Applicant(s)

GAN ET AL.

Examiner

Jeffrey Siew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in PCT EP99/02242 on 4/1/99 and DE 19814982.5 filed 4/1/99. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

### ***Oath/Declaration***

2. The oath claims foreign priority to DE19814682.5 filed 4/1/98. It is unclear as to whether the year is 1999 or 1998. Clarification or correction is required.

### ***Specification***

3. The Brief Description of Drawings refers to Figure 1 and 2 but there are Figures 1A and 1B and 2A and 2B. There is no Figure 1 and 2. Appropriate Correction is required.

### ***Claim Rejections - 35 USC § 101***

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4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 16 provides for the use of device, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

B) Claims 1-5 is confusing because they are drawn to a method but no clear and defined steps are recited. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion and clearly refer back to the preamble of the claim. See *ex parte Erlich*, 3 USPQ2, p. 1011 (Bd. Pat. A.P. In. 1986). It is suggested that all claims be amended to set forth active steps.

C) The phrase "characterized " renders claims 1-5 indefinite. It cannot be determined metes and bounds of the phrase. It is strongly suggested that the phrase be deleted and the use of active steps be employed (see above paragraph).

D) The number designations e.g. (2) throughout claims 1-16 render the claims indefinite. It cannot be determined to what the designations refer to and what limitations are being associated with it.

E) The term especially render claims 1,2,4,7,8 & 10 indefinite. It cannot be determined whether the claim incorporates the following limitation or not. The phrase should be deleted.

F) The term preferably renders claim 12 indefinite because it cannot be determined whether the claim incorporates the following limitation or not.

G) Claim 6 is grammatically confusing in the phrase “means for quantifying that comprises a detector” It is suggested the word “comprising” be used.

H) It is unclear as to what selection of light source is being covered by the claim 8. It is suggested that Markush language be employed.

I) In claim 11 scanner lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-7 & 16 rejected under 35 U.S.C. 102(e) as being anticipated by Higuchi et al (US 6,171,785 Jan. 9, 2001).

Higuchi et al teach PCR amplification of various biological materials such body fluids, feces, sputum saliva (see col. 6 lines 65-67). They teach PCR amplification detection and monitoring to distinguish high molecular weight DNA and primer dimers using light scattering. A spectra fluorometer measures light scattering. They even teach a ELIZA plate reader designed

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to excite and measure fluorescence .e.g. CytoFluor 2300 machine which can read microtiter plates before and after amplification.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higuchi et al (US 6,171,785 Jan. 9, 2001) in view of Hang et al (US6,121,603 Sept 19,2000).

The teachings of Higuchi et al are described previously.

Higuchi et al do not teach scanner.

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Hang et al teach a confocal scanning imaging device for illuminating multiplaced objects with a dichroic mirror and CCD (see whole doc. esp. abstract and col. 14 line 40-41).

One of ordinary skill in the art would have been motivated to apply Hang et al's scanner Higuchi et al's assay in order to detect scattered light. It would have been prima facie obvious to apply Hang et al's scanning detector to Higuchi et al's assay in order to analyze the light emission results during amplification.

9. Claims 14 & 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higuchi et al (US 6,171,785 Jan. 9, 2001) in view of Lehnen (US5,567,627 Oct. 22, 1996).

The teachings of Higuchi et al are described previously.

Higuchi et al do not teach two detectors.

Lehnen et al teach the use of two detectors for detecting scattered light for detection and using a computer for further analysis (see col. 9 lines 44-47).

One of ordinary skill in the art would have been motivated to apply Lehnen et al's method of using two detectors to Higuchi et al's assay in order to detect scattered light. As Lehnen states that two detectors capture both forward and side scattered which relates to size of the analyte, it would have been prima facie obvious to apply Lehnen et al's detectors and computers to Higuchi et al's assay in order to analyze the light emission results during amplification.

SUMMARY



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10. No claims allowed.

### CONCLUSION

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703)-308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Fax (703) 308-4556 or (703) 308-4242.

  
Jeffrey Siew

November 16, 2001